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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/527,925	09/15/2005	Raymond John Steptoe	18749	8585

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EXAMINER	
LI, QIAN JANICE	
ART UNIT	PAPER NUMBER
1633	
MAIL DATE	DELIVERY MODE
10/03/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/527,925	STEPTOE ET AL.	
	Examiner	Art Unit	
	Q. JANICE LI, M.D.	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12/19/07*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-8 and 10-16* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8, 10-16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *16 March 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 6/25/08 has been entered.

The amendment and response filed 6/25/08 are acknowledged. Claims 1-3, 6, 7, 10 have been amended. Claims 9 and 17 have been canceled. Claims 1-8, 10-16 are pending and under current examination.

Unless otherwise indicated, previous rejections that have been rendered moot in view of the amendment to pending claims will not be reiterated. The arguments in 6/25/06 response would be addressed to the extent that they apply to current rejection.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of

the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-8, 10, 12-16 stand and newly rejected under 35 U.S.C. 103(a) as being unpatentable over *Bochan et al.* (Transplant proc 1999;31:690-1), in view of *Inukai et al.* (Jpn J Pharmacol 1993;61:221-7) and *Burt et al.* (Autoimmunity Rev 2002;1:133-8), for reasons of record and following.

Bochan teaches a method for treating insulin-dependent diabetes in a subject comprising collecting a sample of hematopoetic stem cells from the bone marrow of the rat, infecting the HSCs with a recombinant AAV vector expressing rat proinsulin, and reintroducing the transfected HSCs to rats with STZ-induced diabetes. *Bochan* reported transgene expression in several tissues of the rat, and the expression lasted for up to 6 wks, and in the short term, they were able to reverse STZ-induced diabetes (e.g. figs and page 691).

Bochan does not mention preventing or reducing the risk of development of diabetes. *Inukai* supplemented the deficiency by a showing that the means for reversing the course of diabetes should also be capable of preventing and reducing the risk of developing diabetes. *Inukai* teaches using a novel reductase inhibitor TAT for treating

diabetic neurophathy in rats, and reports the dosage as 8.8 mg/kg/day for prevention and 9.0 mg/kg/day for reversal (e.g. the abstract).

Although *Bochan et al* do not specify whether the HSCs injected to STZ-diabetic rats are autologous, this was known in the art as taught by *Burt et al* (§ 4). Although *Bochan et al* conducted the experiment in rat, and used rat proinsulin II, it is clear the investigation was a feasibility study for treating diabetes in humans.

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method taught by *Bochan et al,* for preventing and treating human diabetes upon completion of necessary pre-clinical studies and use autologous HSCs and human insulin in a human subject, with a reasonable expectation of success. The ordinary skilled artisan would have been motivated to modify the claimed invention because the ultimate goal of animal study is to develop a treatment strategy for treating human diabetes. Thus, the claimed invention as a whole was *prima facie* obvious in the absence of evidence to the contrary.

Response to Arguments

In the remarks, the applicant argues that *Bochan* teaches reversing diabetes whereas instant claims are directed to prevention and reducing the risk of the developing diabetes.

The argument has been fully considered but found not persuasive. This is because it was common knowledge in the art that prevention and treatment of a disease go hand in hand. For any given treatment regimen, the underlying mechanism for

reversing the course of diabetes generally should be the same for prevention. In fact, it is harder to achieve course reversal for a disease than to prevent or reduce the risk of developing the disease. This was shown by the newly cited reference *Inukai et al,* and was also shown by *Tian et al.* (J Immunol 2007;179:6762-9), who teaches using transduced autologous hemopoietic stem cells for prevention and reversal of diabetes. Accordingly, the claimed invention as a whole was *prima facie* obvious.

The applicant then asserts that the Office analysis was entirely erroneous regarding autologous transplantation, the previous remarks and exhibits were directed to the general state of the art, and no where on record the applicant admitted non-enablement of the claimed method.

In response, the claimed invention is drawn to using autologous HPC for preventing insulin-dependent diabetes, yet the argument and exhibits were directed to evidence showing that allogeneic, but not autologous, transplantation resulted in marked amelioration of rheumatoid arthritis. It would have suggested to the skilled the evidence does not appear to support instant claims.

Claim 11 stands rejected under 35 U.S.C. 103(a) as being unpatentable over *Bochan et al* (Transplant proc 1999;31:690-1), in view of *Inukai et al.* (Jpn J Pharmacol 1993;61:221-7) and *Burt et al* (Autoimmunity Rev 2002;1:133-8) as applied to claims 1-8, 10, 12-16 above, further in view of *Slavin et al* (USP 6428782), for reasons of record and *supra.*

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Q. JANICE LI, M.D.** whose telephone number is **571-272-0730**. The examiner can normally be reached on 9 AM -7:00pm, Monday through Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Joseph Woitach** can be reached on **571-272-0739**. The **fax** numbers for the organization where this application or proceeding is assigned are **571-273-8300**.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

For all other customer support, please call the USPTO Call Center (UCC) at **800-786-9199**.

/Q. JANICE LI, M.D./
Primary Examiner, Art Unit 1633

QJL
October 3, 2008